EXHIBIT U

ATTACHMENT 6: RISK MANAGEMENT

Attached is the original Risk Analysis which was prepared in 2000.
The Risk Analysis will be updated according to ISO 14971: 2007. Once it is available, this section will be updated.

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ETHICON, INC.
a Johnson & Johnson company

P.O. BOX 151
SOMERVILLE, NEW JERSEY 08876-0151

November 11, 2000

Soft Prolene Mesh Device Final Design Safety Analysis (DDSA) - Summary

Overview:
The Soft PROLENE Mesh product is a single use (functioning as a bridging material) polypropylene mesh product that will be provided sterile, packaged ready for use.

An intermediate DDSA was completed and approved by the development team in March of 2000.

Intermediate DDSA Approvers:
J. O'Malley - Product Marketing
C. Whiteman - Process/Manufacturing Engineering
M. Pamphille - Corp. Quality Engineering
K. Lessig - Regulatory Affairs
G. O'Brien - Cornelia Quality Engineering
R. Rousseau - R&D

Also, a review of complaints for similar products (Mersilene and Prolene Mesh) was conducted in September of 2000 for Human Factors. (See attached report)

Conclusions:
There are 5 hazards, all at an acceptable level.
No risk reduction was required.

Assumptions:
Assumptions are contained in the DDSA form (Pg. 14).

Matt McGill
Quality Engineer

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ETHICON, INC.
a Johnson & Johnson company

P.O. BOX 151
SOMERVILLE, NEW JERSEY 08876-0151

September 5, 2000

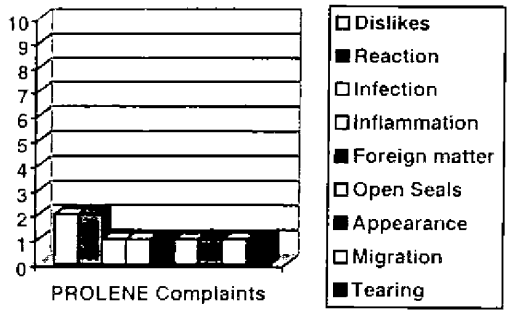
TO: Matthew McGill
FROM: R. Rousseau
CC:

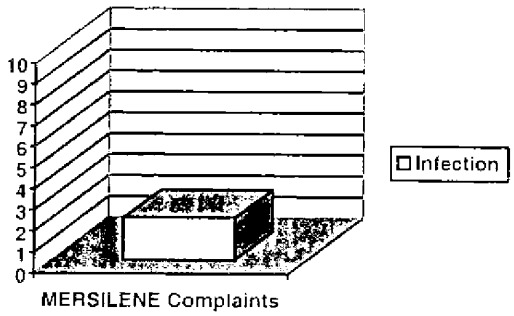
Subject: **Soft PROLENE Mesh - Complaint Review of Similar Products for Human Factors**

Matt,

As we had discussed during the project team meeting, held on 08/23/00, I have received an updated list of the product complaints for the standard PROLENE Mesh and for Mersilene Mesh from the World Wide Quality department(attached). The complaint listing was for the time period of May 1999 through August 2000. During this time there were a total of eleven (11) complaints for the PROLENE Mesh and two (2) complaints for the Mersilene Mesh product.

The type of complaints that were received are plotted in the following histograms:





The sales for this time period were also provided by Kiko Morillo (attached). During this time frame, 179,126 sheets of PROLENE mesh and 7940 sheets of Mersilene mesh were sold. Based upon these sales results, the complaint rate for PROLENE mesh was 0.006% and for Mersilene mesh was 0.025 %.

The lack of a single complaint type / trend indicates that Human factors induced failure modes are not typical in either the heavy weight(PROLENE) or light weight(Mersilene) meshes. If you have any questions, please contact me at 3215.

Robert Rousseau
Staff Engineer, Suture Technologies

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prod_cd	lot_no	complaint_	complaint_	rcvd_mode	event_dt	alert_dt	fmly_cd	cat_desc_txt	cat_desc_t	qty_invld_	cat_lvl1_cc	cat_lvl2_cd
99999M1	UNK	10005768	C	N	UNK	5/10/2000	M1	Suture Related	INFECTIOI	1	1	19
99999M1	UNK	10005049	C	L	UNK	3/17/2000	M1	Suture Related	INFECTIOI	1	1	19

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prod_cd	lot_no	complaint_no	complaint file_stat_cd	rcvd_mode_cd	event_dt	alert_dt	cls_dt	cls_oper_id	complaint_typ_dt	crt_dt	add_dt	updt_dt	fmly_cd	cat_desc_txt	cat_desc_txt	qty_invld_amt
PMH	MGE034	10001987	C	P		8/16/99	9/13/99	ADONETZ	8/16/99	8/16/99	8/16/99	9/13/99	PB		APPEARANCE	1
						13:04:54	14:51:10		13:04:54	13:04:54	13:04:54	14:51:10		Suture Related		
PMH	UNK	10002319	C	F	09/24/1999	9/24/99	10/4/99	JROSADO	10/4/99	10/4/99	10/4/99	10/4/99	PB		DISLIKES	1
						00:00:00	15:45:42		15:12:14	15:12:14	15:12:14	15:45:42		Suture Related	PRODUCT	
PML	UNK	20001767	C	F	UNK	1/24/00	2/14/00	SSPOKANE	1/28/00	1/28/00	1/28/00	2/14/00	PB		DISLIKES	1
						00:00:00	17:12:45		10:13:54	10:13:54	10:13:54	17:12:45		Suture Related	PRODUCT	
PMS	UNKNOWN	20001098	C	F	Unknown	7/24/99	8/12/99	LBERGER	7/29/99	7/29/99	7/29/99	8/12/99	PB		INFECTION	1
						00:00:00	09:14:12		12:22:43	12:22:43	12:22:43	09:14:12		Suture Related		
PMI	UNK	10001386	C	P	05/03/1999	5/3/99	5/24/99	ADONETZ	5/6/99	5/6/99	5/6/99	5/24/99	PB		REACTION	1
						00:00:00	10:06:01		11:06:52	11:06:52	11:06:52	10:06:01		Suture Related	(Do not use)	
99999PB	UNK	10001381	C	P	UNK	5/4/99	5/24/99	ADONETZ	5/4/99	5/4/99	5/4/99	5/24/99	PB		REACTION	1
						16:10:40	09:20:21		16:10:40	16:10:40	16:10:40	09:20:21		Suture Related	(Do not use)	
PMII	MK3806	10005408	C	P	04/12/2000	4/12/00	5/24/00	ADONETZ	4/13/00	4/13/00	4/13/00	5/24/00	PB		TEARING	1
						00:00:00	16:02:17		14:32:20	14:32:20	14:32:20	16:02:17		Suture Related		
PMM	GB2013	10001662	C	P	UNK	6/3/99	4/11/00	ADONETZ	6/18/99	6/18/99	6/18/99	4/11/00	PB		Migration of Mesh	1
						00:00:00	10:42:20		08:21:28	08:21:28	08:21:28	10:42:20		Suture Related		
99999PB	UNK	10004348	C	P	12/07/1999	1/20/00	3/7/00	ADONETZ	1/20/00	1/20/00	1/20/00	3/7/00	PB		Inflammation	1
						14:51:53	15:53:11		14:51:53	14:51:53	14:51:53	15:53:11		Suture Related		
PMH	LPP778	10003263	C	F	11/16/1999	11/12/99	12/20/99	LDEJESU	11/15/99	11/15/99	11/15/99	12/20/99	PB		FOREIGN	1
						00:00:00	15:17:35		18:19:26	18:19:26	18:19:26	15:17:35		Suture Packaging	MATTER	
PHSE	LG6439	10001729	C	P	UNK	6/29/99	8/25/99	JROSADO	6/29/99	6/29/99	6/29/99	8/25/99	PB		OPEN SEALS	1
						12:39:44	15:31:17		12:39:44	12:39:44	12:39:44	15:31:17		Suture Packaging		

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	MAY '99	JUN '99	Q3 '99	Q4 '99	Q1 '00	APR '00	TOTAL	AVG PRICE PER SHEET '99	TOTAL SHEETS
PMH (6 X 0000 PROL MESH)	$ 187,118.00	$ 201,430.00	$ 516,909.00	$ 537,794.00	$ 491,911.00	$ 227,731.00	$ 2,162,893.00	45	48064.28889
PMI (5 X 3 PROL)	$ 286,736.00	$ 327,797.00	$ 437,749.00	$ (10,063.00)	$ (2,832.00)	$ -	$ 1,039,387.00	36	28871.86111
PMII ()	$ -	$ -	$ 404,718.00	$ 1,015,721.00	$ 793,003.00	$ 329,672.00	$ 2,543,114.00	36	70642.05556
PML (12 X 12 PROL MESH)	$ 139,112.00	$ 175,180.00	$ 485,629.00	$ 552,793.00	$ 364,106.00	$ 168,439.00	$ 1,885,259.00	106	17785.46226
PMLK (2.4 X 5.4 PROL)	$ 4,323.00	$ 15,384.00	$ 43,192.00	$ 53,059.00	$ 37,921.00	$ 10,649.00	$ 164,528.00	60	2742.133333
PMM (6 X 6 PROL MESH)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	45	0
PMS (2.5 X 4.5 PROL MESH)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	36	0
PMSK (4 X 1.8 PROL)	$ 14,843.00	$ 15,306.00	$ 62,233.00	$ 87,256.00	$ 51,761.00	$ 36,650.00	$ 268,049.00	47	5703.170213
PMXL ()	$ -	$ -	$ -	$ 5,028.00	$ 14,450.00	$ 7,261.00	$ 26,739.00	44	607.7045455
PMXS (4 X 1 PROL)	$ 11,088.00	$ 7,977.00	$ 33,132.00	$ 31,261.00	$ 38,748.00	$ 19,163.00	$ 141,369.00	30	4712.3
RML (12 X 12 MERS MESH)	$ 17,072.00	$ 36,467.00	$ 104,934.00	$ 108,663.00	$ 55,976.00	$ 112,009.00	$ 435,121.00	95	4580.221053
RMS (2.5 X 4.5 MERS MESH)	$ 6,098.00	$ 3,432.00	$ 13,628.00	$ 18,044.00	$ 8,335.00	$ 27,806.00	$ 77,343.00	23	3362.73913
						TOTAL	$ 8,743,802.00		187071.9361

ETH.MESH.06399210

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PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	**REVISION: 2**
	REVISION DATE: 11/8/00
Product Name:	Soft PROLENE Mesh
Product Code:	SPMXS (1x4), SPMS (2.5x4.5), SPMII (3x6), SPMH (6x6), SPMLI (10x10), SPMXXL (12x14)
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	**ASSOCIATE NAME**
Development Engineer/Scientist:	Robert A. Rousseau
Process Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Matt McGill
Regulatory Affairs:	Karen Lessig
Product Marketing:	Kiko Morillo

DISPOSITION/APPROVAL:

Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ____: No.
Manufacturing Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ____: Yes; ____: No.
Quality Assurance Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ____: No.
Regulatory Affairs	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ____: No.

Medical Director: _____ 11/14/00

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OP650-010
CP1998SEF001
Appendix 1

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 2
	REVISION DATE: 11/8/00
Product Name:	Soft PROLENE Mesh
Product Code:	SPMXS (1x4), SPMS (2.5x4.5), SPMII (3x6), SPMH (6x6), SPMLI (10x10), SPMXXL (12x14)
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	**ASSOCIATE NAME**
Development Engineer/Scientist:	Robert A. Rousseau
Process Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Matt McGill
Regulatory Affairs:	Karen Lessig
Product Marketing:	Kiko Morillo

DISPOSITION/APPROVAL:

Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ____: Yes; ____: No.
Charlotte Whiteman **Manufacturing Engineer**	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ____: No.
Quality Assurance Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ____: Yes; ____: No.
Regulatory Affairs	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ____: Yes; ____: No.

Medical Director: _____

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DEVICE DESIGN SAFETY ASSESSMENT (DDSA) SUMMARY REPORT
(Revision 2)

DEVICE: (*Provide a description of the overall device system*) A **non-absorbable polypropylene mesh, manufactured out of 3.5-mil diameter PROLENE* monofilament fiber. The product is used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing (see attached Product Insert)**

SCOPE of the DESIGN SAFETY ASSESSMENT: (*Define the scope of this risk assessment*)

This risk assessment was completed on (*check one*): __X__ Device ____Subsystem ____Component

This DDSA is applicable to the Soft PROLENE mesh product and will identify any hazards associated with this new product offering.

Define the intended use of the reviewed item:

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result (see attached Product Insert)

Briefly describe the revision to the device or sub-system which preceded a revision to the DDSA:

The standard non-absorbable polypropylene mesh currently marketed is manufactured out of 5-mil PROLENE monofilament fiber. The construction utilized for the Soft PROLENE mesh is manufactured out of 3.5-mil monofilament fiber with a new knit pattern. This new pattern, coupled with the finer diameter fiber, yields a mesh product with larger porosity, lower fabric density and improved flexibility. Revision 2 is the final DDSA.

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ACTIVITY	YES/NO /NA	FILE REFERENCE	COMMENT
All qualitative and quantitative characteristics that could affect safety have been listed including their defined limits.	YES	D&D Plan & Material Specification #729-007	Statement of Requirements & Product Characteristics
The intended use of the device is clearly defined, including: Indications/Contraindications and intended use The intended user, his required skill and training Interaction of device with the patient as user: The operational, transport, cleaning and storage environments have been considered:	YES	Product Insert -	Indications Same as for Standard PROLENE Mesh and Mersilene Mesh
Long term use of equivalent product has been considered from both the positive and negative perspective. Clinical/Scientific reports, both internal and published: Device failure reports:	YES	See Performance Requirements/Clinical applications of D&D	Raw Materials and Indications for device are the same as Standard PROLENE mesh.
The contact conditions and timing with the patient have been considered.	YES	See Performance Requirements/Clinical applications of D&D	Raw Materials and Indications for device are the same as Standard PROLENE mesh.
Materials and components used for fabrication and manufacture have been considered. Chemical nature, quantitative formulation, additives, processing aids, monomers, catalysts, residues: Concentration, availability, toxicity: Biodegradation aging and corrosion: Previous use of this material, and long term effectiveness in equivalent application can be demonstrated: Appropriate Biocompatibility testing to EN 30993:	YES	Soft PROLENE Mesh Biocompatibility Strategy	Raw materials are chemically unchanged – The Standard PROLENE Resins utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh.
The sterility of the device and its potential reuse, number of resterilizations possible and sterilization method, device storage, shelf-life, and disposal have been considered.	YES	Product Insert -- Warnings section & 1) Sterilization 2) Storage Stability	Raw materials are unchanged – Standard PROLENE Resin

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		Strategy	
The accuracy and precision of measurement parameters and their interpretation has been considered.	N/A	N/A	N/A
The need for routine maintenance or calibration, and the method of provision has been considered.	N/A	N/A	N/A
Interactions with other devices or drugs, and any potential problems have been considered.	YES	N/A	Raw materials are chemically unchanged – The Standard PROLENE Resins utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh.
Delayed or long term use, ergonomic and accumulative effects have been considered	YES	N/A	Raw materials are chemically unchanged. The revised construction exceeds the burst and suture pullout strengths of Mersilene Mesh and exhibits a flexibility that is greater than Mersilene Mesh and lower than standard PROLENE mesh. Based upon the mechanical and chemical criteria utilized to develop this material, negative tissue responses or new negative long term implant effects are not anticipated.
A PBOM has been defined.	YES	N/A	
A requirement or finished goods specification is available.	YES	D&D – Statement of Requirements	FG729-002 will be revised
Manufacturing and Material specifications are available.	YES	N/A	MS 729-007 drafted.
Surgical technique, labels, warnings and other instructions for use (cleaning, sterilization, use, maintenance, and disposal) are available.	YES	Product Insert	See package Insert
Device marketing brochures, or other sales literature, have been considered.	Yes	Indications&Claims Defined	Sales Literature to be developed

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

5

CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
1 Intended Use	1) Is special training of the intended user needed?	X		If yes, please attach training plan
	2) Does use of the device impose any ergonomic factors or effects?	X		If yes, please attach plan.
	3) Are there any environmental factors that could influence safety/function of the device?	X		If yes, please define the limits.
	4) Can the patient control or influence the use of the device?	X		If yes, please define the training plan for the user.
	5) Is device safety/functionality compromised based upon the patient (such as elderly, diabetic, handicapped, or other)?	X		If yes, please define the nature of the compromise and the limits.
2 Patient Contact	6) Does device use utilize surface contact to the patient?		X	Permanent prosthetic implant.
	7) Does device use utilize invasive contact with the patient?		X	Permanent prosthetic implant.
	8) Does device use require implantation?		X	Permanent prosthetic implant.
3 Materials	9) Define the materials utilized in the construction of the device. Highlight those materials that will involve direct patient contact		X	Prolene - Polypropylene (blue pigmented and clear). The processes utilized in the manufacture of the material are unchanged relative to standard PROLENE mesh.
	10) Have the materials been tested for toxicity and biocompatability?		X	DHF: Biocompatibility section - 12/2/99 memo from T. Barbolt.
	11) Have the materials been tested for carcinogenicity, teratology, and mutagenicity (as appropriate)?	X		No change to raw materials from standard PROLENE.

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

6

CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	12) Is the strength of load-bearing materials sufficient for the intended use?		X	The Soft PROLENE Mesh is indicated for the same applications as Mersilene Mesh. The material exceeds the strength specification for Mersilene Mesh - MS726-001 and has greater suture pull-out strength than Mersilene.
4 Energy	13) Is energy delivered to and/or extracted from the patient?	X		If no, proceed to the next section.
	14) Describe the type of energy transferred.	[redacted]		
	15) Is the energy output is controlled, in terms of quality, quantity, and time-function			
5 Substances	16) Are substances delivered to and/or extracted from the patient?		X	Soft PROLENE Mesh
	17) Is the device absorbable?	X		If yes, please attach a listing of all by-products produced during the devices in-situ degradation
	18) If the device is absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations?	X		If yes, please identify the location of appropriate reports.
	19) Is the transfer rate (delivery/extraction) of substances controlled?	X		If yes, please describe how the transfer rate is controlled.
	20) What is the maximum/minimum substance transfer rate?	[redacted]	[redacted]	If appropriate, please attach required information.

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

7

CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
6 Biological Materials	21) Are biological materials processed by the device for subsequent re-use?	X		If not, proceed to the next section.
	22) Is the device disposable?			[redacted]
	23) Are those components contacting biological materials cleanable and sterilizable?			If yes, please specify location of reports.
	24) Are those components contacting biological materials compatible?			If yes, please specify location of reports.
7 Sterility - Supplied Sterile	25) Is the device supplied sterile?		X	If not, please proceed to the next section.
	26) Identify the method of sterilization	[redacted]	[redacted]	Ethylene Oxide - Cycle "J". DHF: Sterility Section - Memo from D. Lasslett.
	27) Is the sterilization method compatible with the materials?		X	No change to existing polymer. Heat setting process, utilized to stabilize the mesh is executed at a temperature approximately three times as great as the temperatures experienced in sterilization.
	28) Are the materials stable after sterilization?		X	No change to existing materials.
	29) Is the device design sterilizable?		X	No change to existing materials.
	30) Is the package designed to provide for sterilization of the device?		X	Packaging unchanged from standard PROLENE Mesh.
	31) Has the shelf life of the system been determined?		X	No change to existing materials - DHF: Storage Stability Committee meeting minutes - 12/9/99.

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	32) Is the device re-usable?	X		If not, please proceed to the next section.
	33) Are there limitations to the number of re-use cycles?	X		If yes, please specify location of reports.
	34) Are there restrictions to sterilization methods utilized by the user of the device?	X		If yes, please specify location of reports.
8 Sterility - Supplied Non-Sterile	35) Is the device to be sterilized by the user?	X		If not, please proceed to the next section.
	36) Is the method of sterilization and cycle parameters defined?			If yes, please specify location of reports.
	37) Is the packaging of the product during sterilization specified?			If yes, please specify location of reports.
	38) Does sterilization validation data exist for the recommended sterilization cycle?			If yes, please specify location of reports.
	39) Were other methods of sterilization examined?			If yes, please specify location of reports.
	40) Has the shelf life of the system been determined?			If yes, please specify location of reports.
9 Environment	41) Is the device intended to modify the patient environment?	X		If not, please proceed to the next section.
	42) What is the effect of temperature on the system performance?			If yes, please specify location of reports.
	43) What is the effect of humidity on the system performance?			If yes, please specify location of reports.
	44) What is the effect of atmospheric gas concentration on system performance?			If yes, please specify location of reports.
	45) What is the effect of pressure on system performance?			If yes, please specify location of reports.

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
10 Measurements	46) Does the device make measurements?	X		If not, please proceed to the next section.
	47) Is there interference of the desired parameter with other possible measurements?			If yes, please specify location of reports.
	48) Is the accuracy of the measurement known at point of use?			What is the accuracy?
	49) Is the precision of the measurement known?			What is the precision?
11 Interpretive	50) Are conclusions presented by the device based upon measurements, input, or acquired data?	X		If yes, please specify location of software validation reports.
12 Interactions	51) Is the device intended to control or interact with other devices or drugs?	X		If not, please proceed to the next section.
	52) If the device is used with other devices or drugs, is there a potential interaction?	X		If yes, please specify
	53) Does the interaction render any safety or functional changes to the device?			If yes, please specify
	54) Does the interaction render any safety or functional changes to the other device?			If yes, please specify
13 Extraneous Unwanted Energy or Substances	55) Are there any unwanted outputs of energy or substances?	X		If not, please proceed to the next section.
	56) Does noise affect the device output?			If yes, please define the limits.
	57) Does vibration affect the device output?			If yes, please define the limits.
	58) Does heat affect the device output?			If yes, please define the limits.
	59) Does ionizing radiation affect the device output?			If yes, please define the limits.
	60) Does non-ionizing radiation affect the device output?			If yes, please define the limits.

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	61) Does UV/visible/IR radiation affect the device output?			If yes, please define the limits.
	62) Do leakage currents affect the device output?			If yes, please define the limits.
	63) Do electric/magnetic fields affect the device output?			If yes, please define the limits.
	64) Do contact temperatures affect the device output?			If yes, please define the limits.
	65) Does discharge of chemicals affect the device output?			If yes, please define the effect.
	66) Does discharge of waste products affect the device output?			If yes, please define the effect.
	67) Does discharge of body fluids affect the device's output?			If yes, please define the effect.
14 Environmental Influences	68) Is the device susceptible to environmental influences?	X		If not, please proceed to the next section.
	69) Do shipping temperatures affect device safety or functionality?			If yes, please state the limits.
	70) Does storage temperatures, humidity, or light affect device safety or functionality?			If yes, please state the limits.
	71) Does spillage on the device affect safety or functionality?			If yes, please state the limits.
	72) Do fluctuations in the power affect the device output or safety?			If yes, please state the limits.
	73) Does variation in the operating temperature, humidity, or light affect the device output or safety?			If yes, please state the limits.
	74) Does variation in the operating humidity affect the device output of safety?			If yes, please state the limits.
15 Accessories	75) Are there essential consumables or accessories associated with the device?	X		If yes, please specify

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
16 Preventative Maintenance	76) Is preventative maintenance necessary?	X		If not, please proceed to the next section.
	77) Can the operator perform preventative maintenance?			
	78) Is a specialist needed to perform preventative maintenance?			
17 Calibration	79) Is calibration necessary?	X		If not, please proceed to the next section.
	80) Can the operator calibrate the device?			
	81) Is an external calibration of the device needed?			
	82) Is the calibration frequency defined?			
18 Software	83) Does the device contain software?	X		If not, please proceed to the next section.
	84) Can the operator access the software code?			
	85) Are there means to prevent the operator from modifying the code?			
19 Shelf-life	86) Does the device have a restricted shelf life?		X	5 years - No change to existing materials - DHF: Storage Stability Committee meeting minutes - 12/9/99.
	87) Does the package contain an indicator for stability?		X	Expiration date labeling 95 years).
20 Long-term Effects	88) Are there any delayed or long-term user effects?	X		If yes, please specify.
	ADD ADDITIONAL CHARACTERISTICS, AS NEEDED			

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USE RELATED HAZARDS

Place an "X" in the box appropriate for the device being evaluated.	RESPONSE		ACTION
ISSUE	NO	YES	
1) Have safety or efficacy issues occurred in the use of predicate, or other similar, devices?	X		If yes, explain how this design mitigates issues.
2) Could the user incorrectly setup the device that may potentially result in a safety or efficacy event?	X		If yes, explain actions needed to address this event
3) Identify the critical steps in setting up and operating the device. Can these functions be performed adequately by all of the intended users?		X	[1]See steps at the end of this checklist.
4) Does this device replace an existing device for the same medical procedure or indication for use?		X	If yes, continue to #5; if no, continue to #7
5) Does the device visually resemble the existing device?		X	If yes, continue to #6; if no, continue to #7
6) Will the device operate as intended if it is operated in the manner utilized for the existing device?		X	If yes, continue to #7; if no, explain ramifications.
7) Is the user likely to use the device in a manner other than that described in the Instructions for Use?	X		If yes, explain ramifications
8) Is special training needed for the safe and effective use of the device?	X		If yes, provide plan for accomplishing this training
9) If storage and maintenance requirements are not followed, could use of the device result in an unsafe or ineffective use?	X		If yes, provide plan to mitigate the event.
10) Is safe and effective use of the device complex? Under high stress conditions, could the user become confused such that the device results in an unsafe condition?	X		If yes, provide plan to mitigate the event
11) Are the auditory and visual alarms appropriate for all users and use environments?	X		Device is an implant and does not have alarms.
12) If necessary device accessories are expired, damaged, missing, or different from those recommended, could use of the device result in an unsafe or ineffective treatment?	X		No accessories required for use.
13) Is safe operation of the device resistant to "typical" handling?		X	If no, provide plan to mitigate the event

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USE RELATED HAZARDS

14.)Could device safety be affected if power is lost or disconnected (inadvertently or purposefully); if its battery is damaged, missing or dead?	X		If yes, provide plan to mitigate the event
15.)Is the status of the device's connection to the patient apparent where necessary?	X		Device is an implant and does not connect to the patient for feedback/monitoring.

[1]Critical steps in setting up and operating the device:

First the mesh is pulled for the case. The circulating nurse makes sure that the proper product was pulled for the case prior to introducing it to the sterile field. The scub nurse will either grab it out of the packet or let if fall on the mayo stand. The mesh is then given to the surgeon by the scrub nurse. If the scrub is familiar with the surgeon's needs he or she may cut or modify the mesh for the surgeon. If not, the surgeon may cut or modify to fit his needs then insert it in the patient. Then the surgeon may attach it in place using sutures, staples or a tacker.

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DEVICE DESIGN SAFETY ASSESSMENT (DDSA) FORM
Soft PROLENE Mesh Project: Intermediate - Revision 1

LINE NUMBER	HAZARD	SEVERITY of HARM	PROBABILITY of HAZARD	RISK LEVEL	FAULT CLASS	COMMENT	REFERENCES
1	Loss of Mechanical Integrity	3	1	II	C	Risk acceptable, Material is stronger than Mersilene Mesh with same indications. No action required.	DHF: D&D Statement of Requirements, Material must exceed strength criteria of Mersilene Mesh (MS726-001)
2	Unavailable Operating Instructions	1	2	I	C	Risk is acceptable, unchanged relative to currently marketed device. No Action required.	N/A
3	Fraying	1	2	II	C	Risk acceptable, the resistance to fraying is improved relative to currently marketed Mersilene. No action required.	Three bar knitting, by design, limits the ability of the fibers to fray along the edges of the mesh.
4	Tearing	2	2	II	C	Risk acceptable, improved relative to currently marketed Mersilene mesh. No action required.	DHF: D&D statement of requirements and bench-top feasibility test reports.
5	Suture Pull out	2	2	II	M	Risk acceptable, improved relative to currently marketed Mersilene mesh. No action required.	DHF: Feasibility bench-top test report from Ethicon GmbH.

Assumptions:
1) Only Personnel skilled in surgery have access to the device.
2) Biocompatibility and toxicology issues are proven as non-existent for PROLENE material.
3) Intended use is defined as implantation for abdominal wall repair.
4) Existing Mersilene mesh product is suitable for intended applications based upon historical results.
5) Hazards listed are new and unique to the new construction device, packaged as intended to be marketed, relative to Mersilene mesh product

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PROLENE® *Soft*

Polypropylene Mesh

Nonabsorbable Synthetic Surgical Mesh

DESCRIPTION

PROLENE® Soft polypropylene mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE® Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

PROLENE Soft mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

ACTIONS

PROLENE Soft mesh is a nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Animal studies show that implantation of PROLENE mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INDICATIONS

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICTIONS

When this mesh is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows.

PROLENE Soft mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

WARNINGS

PROLENE Soft mesh is provided by ETHICON, INC. as a sterile product. Resterilization of the device is NOT recommended. However, testing has demonstrated that unused PROLENE Soft mesh that has been removed from the package and reprocessed will not be adversely affected when exposed not more than one time to conventional steam autoclave conditions of 250°F (121°C) for 20 minutes. Processing under any other condition or by any other means is neither recommended nor endorsed by ETHICON, INC. PROLENE Soft mesh should not be flash autoclaved.

If this product should become stained with blood or soiled, it should not be resterilized for reuse.

When reprocessed as outlined above, it is the responsibility of the end-user to assure sterility of the product via a validated sterilization process, as ETHICON, INC. has no control over environmental conditions the product may encounter prior to, during, or after reprocessing.

PRECAUTIONS

A minimum of 6.5mm (1/4") of mesh should extend beyond the suture line.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, and extrusion.

INSTRUCTIONS FOR USE

It is recommended that nonabsorbable sutures be placed 6.5mm to 12.5mm (1/4" to 1/2") apart at a distance approximately 6.5mm (1/4") from edge of the mesh. Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

HOW SUPPLIED

PROLENE Soft mesh is available in single packets as sterile, clear sheets with blue stripes.

ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

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OP650-010
CP1998SFF001
Appendix I

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 1
[redacted]	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	**ASSOCIATE NAME**
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley

DISPOSITION/APPROVAL:

Development Engineer/Scientist

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one) ___: Yes; ___: No

Manufacturing Engineer

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one) ___: Yes; ___: No.

Quality Assurance Engineer

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one) X : Yes; ___: No.

Regulatory Affairs

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one) ___: Yes; ___: No.

Medical Director: _____

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Appendix 1

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	**ASSOCIATE NAME**
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley

Accept

DISPOSITION/APPROVAL:

Development Engineer/Scientist

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ___ Yes; ___ No.

Jody O'Malley 3/27/00

Manufacturing Engineer

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ___ Yes; ___ No.

Quality Assurance Engineer

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ___ Yes; ___ No.

Regulatory Affairs

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ___ Yes; ___ No.

Medical Director: _____

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PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	**REVISION: 1**
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	**ASSOCIATE NAME**
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley
DISPOSITION/APPROVAL:	
Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ___: Yes; ___: No.
Charlotte Whiteman **Manufacturing Engineer**	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ___: No.
Quality Assurance Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ___: Yes; ___: No.
Regulatory Affairs	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ___: Yes; ___: No.

Medical Director: _____

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CP1998SEF001
Appendix I

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	**ASSOCIATE NAME**
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley

DISPOSITION/APPROVAL:

3/21/00
Development Engineer/Scientist

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ____: No.

Manufacturing Engineer

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ____: Yes; ____: No.

Michaelle Pamphile 3/23/00
Quality Assurance Engineer

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ____: No.

Karen E. Lessig 3-23-00
Regulatory Affairs

I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) ✓: Yes; ____: No.

Medical Director: _____

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DEVICE DESIGN SAFETY ASSESSMENT (DDSA) SUMMARY REPORT

(Revision 1 (Intermediate)– 3/20/00)

DEVICE: (*Provide a description of the overall device system*) A **non-absorbable polypropylene mesh, manufactured out of 3.5-mil diameter PROLENE* monofilament fiber. The product is used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing (see attached Product Insert)**

SCOPE of the DESIGN SAFETY ASSESSMENT: (*Define the scope of this risk assessment*)

This risk assessment was completed on (*check one*): X Device ____Subsystem ____Component

This DDSA is applicable to the Soft PROLENE mesh product and will identify any hazards associated with this new product offering.

Define the intended use of the reviewed item:

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result (see attached Product Insert)

Briefly describe the revision to the device or sub-system which preceded a revision to the DDSA:

The standard non-absorbable polypropylene mesh currently marketed is manufactured out of 5-mil PROLENE monofilament fiber. The construction utilized for the Soft PROLENE mesh is manufactured out of 3.5-mil monofilament fiber with a new knit pattern. This new pattern, coupled with the finer diameter fiber, yields a mesh product with larger porosity, lower fabric density and improved flexibility.

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ACTIVITY	YES/NO /NA	FILE REFERENCE	COMMENT
All qualitative and quantitative characteristics that could affect safety have been listed including their defined limits.	YES	D&D Plan & Material Specification #729-006	Statement of Requirements & Product Characteristics
The intended use of the device is clearly defined, including: Indications/Contraindications and intended use The intended user, his required skill and training Interaction of device with the patient as user: The operational, transport, cleaning and storage environments have been considered:	YES	Product Insert -	Indications Same as for Standard PROLENE Mesh and Mersilene Mesh
Long term use of equivalent product has been considered from both the positive and negative perspective. Clinical/Scientific reports, both internal and published: Device failure reports:	YES	See Performance Requirements/Clinical applications of D&D	Raw Materials and Indications for device are the same as Standard PROLENE mesh.
The contact conditions and timing with the patient have been considered.	YES	See Performance Requirements/Clinical applications of D&D	Raw Materials and Indications for device are the same as Standard PROLENE mesh.
Materials and components used for fabrication and manufacture have been considered. Chemical nature, quantitative formulation, additives, processing aids, monomers, catalysts, residues: Concentration, availability, toxicity: Biodegradation aging and corrosion: Previous use of this material, and long term effectiveness in equivalent application can be demonstrated: Appropriate Biocompatibility testing to EN 30993:	YES	Soft PROLENE Mesh Biocompatibility Strategy	Raw materials are chemically unchanged – The Standard PROLENE Resins utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh.
The sterility of the device and its potential reuse, number of resterilizations possible and sterilization method, device storage, shelf-life, and disposal have been considered.	YES	Product Insert – Warnings section & 1) Sterilization 2) Storage Stability Strategy	Raw materials are unchanged – Standard PROLENE Resin
The accuracy and precision of measurement parameters and their	N/A	N/A	N/A

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interpretation has been considered.	N/A	N/A		N/A
The need for routine maintenance or calibration, and the method of provision has been considered.	N/A	N/A		
Interactions with other devices or drugs, and any potential problems have been considered.	YES	N/A		Raw materials are chemically unchanged – The Standard PROLENE Resins utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh.
Delayed or long term use, ergonomic and accumulative effects have been considered	YES	N/A		The raw materials utilized in the new mesh are chemically unchanged. The revised construction exceeds the burst and suture pullout strengths of Mersilene Mesh and exhibits a flexibility that is greater than Mersilene Mesh and lower than standard PROLENE mesh. Based upon the mechanical and chemical criteria utilized to develop this material, negative tissue responses or new negative long term implant effects are not anticipated.
A PBOM has been defined.	No	N/A		Will be defined during development
A requirement or finished goods specification is available.	YES	D&D – Statement of Requirements		FG729-002 will be revised
Manufacturing and Material specifications are available.	No	N/A		MS 729-006 will be revised
Surgical technique, labels, warnings and other instructions for use (cleaning, sterilization, use, maintenance, and disposal) are available.	YES	Product Insert		See package Insert
Device marketing brochures, or other sales literature, have been	Yes	Indications&Claims		Sales Literature to be

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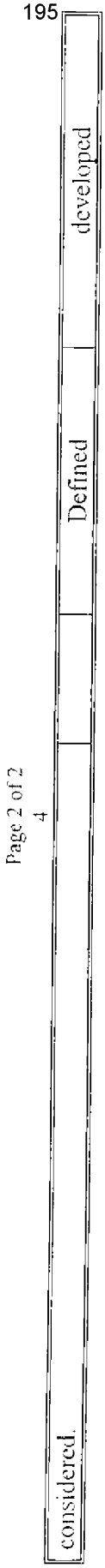

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DEVICE DESIGN SAFETY ASSESSMENT (DDSA) FORM
Soft PROLENE Mesh Project: Intermediate - Revision 1

LINE NUMBER	HAZARD	SEVERITY of HARM	PROBABILITY of HAZARD	RISK LEVEL	FAULT CLASS	COMMENT	REFERENCES
1	Loss of Mechanical Integrity	3	1	II	C	Risk acceptable, Material is stronger than Mersilene Mesh with same indications. No action required.	DHF: D&D Statement of Requirements, Material must exceed strength criteria of Mersilene Mesh (MS726-001)
2	Unavailable Operating Instructions	1	2	I	C	Risk is acceptable, unchanged relative to currently marketed device. No Action required.	N/A
3	Fraying	1	2	II	C	Risk acceptable, the resistance to fraying is improved relative to currently marketed Mersilene. No action required.	Three bar knitting, by design, limits the ability of the fibers to fray along the edges of the mesh.
4	Tearing	2	2	II	C	Risk acceptable, improved relative to currently marketed Mersilene mesh. No action required.	DHF: D&D statement of requirements and bench-top feasibility test reports.
5	Suture Pull out	2	2	II	M	Risk acceptable, improved relative to currently marketed Mersilene mesh. No action required.	DHF: Feasibility bench-top test report from Ethicon GmbH.

Assumptions:

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ppendix IX

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CONTROL PLAN

1) Only Personnel skilled in surgery have access to the device.
2) Biocompatibility and toxicology issues are proven as non-existent for PROLENE material.
3) Intended use is defined as implantation for abdominal wall repair.
4) Existing Mersilene mesh product is suitable for intended applications based upon historical results.
5) Hazards listed are new and unique to the new construction device, packaged as intended to be marketed, relative to Mersilene mesh product.

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET
Soft PROLENE Mesh Project: Intermediate - Revision 1

CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
1 Intended Use	1) Is special training of the intended user needed?	X		If yes, please attach training plan
	2) Does use of the device impose any ergonomic factors or effects?	X		If yes, please attach plan.
	3) Are there any environmental factors that could influence safety/function of the device?	X		If yes, please define the limits.
	4) Can the patient control or influence the use of the device?	X		If yes, please define the training plan for the user.
	5) Is device safety/functionality compromised based upon the patient (such as elderly, diabetic, handicapped, or other)?	X		If yes, please define the nature of the compromise and the limits.
2 Patient Contact	6) Does device use utilize surface contact to the patient?		X	Permanent prosthetic implant.
	7) Does device use utilize invasive contact with the patient?		X	Permanent prosthetic implant.
	8) Does device use require implantation?		X	Permanent prosthetic implant.
3 Materials	9) Define the materials utilized in the construction of the device. Highlight those materials that will involve direct patient contact		X	PROLENE - Polypropylene (blue pigmented and clear). The processes utilized in the manufacture of the material are unchanged relative to standard PROLENE Mesh.
	10) Have the materials been tested for toxicity and biocompatibility?		X	DHF: Biocompatibility Section - 12/2/99 memo from T. Barbolt
	11) Have the materials been tested for carcinogenicity, teratology, and mutagenicity (as appropriate)?	X		No change to raw materials from standard PROLENE.
	12) Is the strength of load-bearing materials sufficient for the intended use?		X	The Soft PROLENE Mesh is indicated for the same

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET
Soft PROLENE Mesh Project: Intermediate - Revision 1

CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
				applications as Mersilene Mesh. The material exceeds the strength specification for Mersilene Mesh - MS726-001 and has greater suture pull-out strength than Mersilene. Based upon the improvements of the mechanical properties of the mesh, coupled with the same intended indications as Mersilene Mesh, the material will be sufficient for it's intended use.
4 Energy	13) Is energy delivered to and/or extracted from the patient?	X		If no, proceed to the next section.
	14) Describe the type of energy transferred.			
	15) Is the energy output is controlled, in terms of quality, quantity, and time-function			
5 Substances	16) Are substances delivered to and/or extracted from the patient?	X		If no, proceed to the next section.
	17) Is the device absorbable?			If yes, please attach a listing of all by-products produced during the devices in-situ degradation
	18) If the device is absorbable, have all of the materials identified above been tested for biocompatibility at the appropriate concentrations?			If yes, please identify the location of appropriate reports.
	19) Is the transfer rate (delivery/extraction) of substances controlled?			If yes, please describe how the transfer rate is controlled.

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	20)What is the maximum/minimum substance transfer rate?			If appropriate, please attach required information.
6 Biological Materials	21)Are biological materials processed by the device for subsequent re-use?	X		If not, proceed to the next section.
	22)Is the device disposable?			
	23)Are those components contacting biological materials cleanable and sterilizable?			If yes, please specify location of reports.
	24)Are those components contacting biological materials compatible?			If yes, please specify location of reports.
7 Sterility - Supplied Sterile	25)Is the device supplied sterile?		X	If not, please proceed to the next section.
7 Sterility - Supplied Sterile	26)Identify the method of sterilization			Ethylene Oxide - Cycle "J". DHF: Sterility Section- Memo from D.Lasslett.
	27)Is the sterilization method compatible with the materials?		X	No change to existing polymer materials and the heat setting process utilized to stabilize the mesh is executed at a temperature approximately three times as great as the temperatures experienced in sterilization.
	28)Are the materials stable after sterilization?		X	No change to existing materials.
	29)Is the device design sterilizable?		X	No change to existing materials.
	30)Is the package designed to provide for sterilization of the device?		X	Packaging unchanged from Standard PROLENE Mesh.
	31)Has the shelf life of the system been determined?		X	No change to existing materials - DHF: Storage

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
				stability Committee meeting minutes - 12/9/99
	32) Is the device re-usable?	X		If not, please proceed to the next section.
	33) Are there limitations to the number of re-use cycles?			If yes, please specify location of reports.
	34) Are there restrictions to sterilization methods utilized by the user of the device?			If yes, please specify location of reports.
8 Sterility - Supplied Non-Sterile	35) Is the device to be sterilized by the user?	X		If not, please proceed to the next section.
	36) Is the method of sterilization and cycle parameters defined?			If yes, please specify location of reports.
	37) Is the packaging of the product during sterilization specified?			If yes, please specify location of reports.
	38) Does sterilization validation data exist for the recommended sterilization cycle?			If yes, please specify location of reports.
	39) Were other methods of sterilization examined?			If yes, please specify location of reports.
8 Sterility - Supplied Non-Sterile	40) Has the shelf life of the system been determined?		X	No change to existing materials DHF: Storage stability Committee meeting minutes - 12/9/99
9 Environment	41) Is the device intended to modify the patient environment?	X		If not, please proceed to the next section.
	42) What is the effect of temperature on the system performance?			If yes, please specify location of reports.
	43) What is the effect of humidity on the system performance?			If yes, please specify location of reports.

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	44) What is the effect of atmospheric gas concentration on system performance?			If yes, please specify location of reports.
	45) What is the effect of pressure on system performance?			If yes, please specify location of reports.
10 Measurements	46) Does the device make measurements?	X		If not, please proceed to the next section.
	47) Is there interference of the desired parameter with other possible measurements?			If yes, please specify location of reports.
	48) Is the accuracy of the measurement known at point of use?			What is the accuracy?
	49) Is the precision of the measurement known?			What is the precision?
11 Interpretive	50) Are conclusions presented by the device based upon measurements, input, or acquired data?	X		If yes, please specify location of software validation reports.
12 Interactions	51) Is the device intended to control or interact with other devices or drugs?	X		If not, please proceed to the next section.
	52) Does the interaction render any safety or functional changes to the device?			If yes, please specify
	53) Does the interaction render any safety or functional changes to the other device?			If yes, please specify
13 Extraneous Unwanted Energy or Substances	54) Are there any unwanted outputs of energy or substances?	X		If not, please proceed to the next section.
	55) Does noise affect the device output?			If yes, please define the limits.
	56) Does vibration affect the device output?			If yes, please define the limits.
	57) Does heat affect the device output?			If yes, please define the limits.
	58) Does ionizing radiation affect the device			If yes, please define the

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Appendix III

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	output?			limits.
	59) Does non-ionizing radiation affect the device output?			If yes, please define the limits.
	60) Does UV/visible/IR radiation affect the device output?			If yes, please define the limits.
	61) Do leakage currents affect the device output?			If yes, please define the limits.
	62) Do electric/magnetic fields affect the device output?			If yes, please define the limits.
	63) Do contact temperatures affect the device output?			If yes, please define the limits.
	64) Does discharge of chemicals affect the device output?			If yes, please define the effect.
	65) Does discharge of waste products affect the device output?			If yes, please define the effect.
	66) Does discharge of body fluids affect the device's output?			If yes, please define the effect.
14 Environmental Influences	67) Is the device susceptible to environmental influences?	X		If not, please proceed to the next section.
	68) Do shipping temperatures affect device safety or functionality?			If yes, please state the limits.
14 Environmental Influences	69) Does storage temperatures affect device safety or functionality?			If yes, please state the limits.
	70) Does spillage on the device affect safety or functionality?			If yes, please state the limits.
	71) Do fluctuations in the power affect the device output or safety?			If yes, please state the limits.
	72) Does variation in the operating temperature affect the device output or safety?			If yes, please state the limits.

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT
	73) Does variation in the operating humidity affect the device output of safety?			If yes, please state the limits.
15 Accessories	74) Are there essential consumables or accessories associated with the device?	X		If yes, please specify
16 Preventative Maintenance	75) Is preventative maintenance necessary?	X		If not, please proceed to the next section.
	76) Can the operator perform preventative maintenance?			
	77) Is a specialist needed to perform preventative maintenance?			
17 Calibration	78) Is calibration necessary?	X		If not, please proceed to the next section.
	79) Can the operator calibrate the device?			
	80) Is an external calibration of the device needed?			
	81) Is the calibration frequency defined?			
18 Software	82) Does the device contain software?	X		If not, please proceed to the next section.
	83) Can the operator access the software code?			
	84) Are there means to prevent the operator from modifying the code?			
19 Shelf-life	85) Does the device have a restricted shelf life?		X	5 Years - No change to existing materials - DHF: Storage stability Committee meeting minutes - 12/9/99.
	86) Does the package contain an indicator for stability?		X	Expiration date labeling (5 years).
20 Long-term Effects	87) Are there any delayed or long-term user effects?	X		If yes, please specify.
	ADD ADDITIONAL CHARACTERISTICS, AS NEEDED			

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CHARACTERISTIC	ISSUE	RESPONSE N/A	RESPONSE YES	COMMENT

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